



HOLY CROSS HOSPITAL

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May 23, 2007

Rex Cowdry, MD
Executive Director
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Dr. Cowdry:

Thank you for the opportunity for Holy Cross Hospital to comment on the proposed Maryland State Department of Health and Mental Hygiene regulations, "Subtitle 24 Maryland Health Care Commission, Chapter 05: Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions Performed in Maryland Hospitals without On-Site Cardiac Surgery."

Holy Cross Hospital strongly supports evidence-based medicine, which is a fundamental basis for its own approach to delivering medical care that its patients can trust. It views the C-PORT study as having the potential to provide the state with scientifically sound data upon which to base public policy decisions and guidance to the health care field in general on non-SOS hospitals providing elective PCI onsite. It also supports the need for the study design to be executed with rigor by all participants.

The goal of this waiver is to accrue patients in a study that has been critically evaluated for patient safety and scientific soundness. In addition, it is critically important to accrue enough patients to reach a sample size sufficient to complete the study within three years, and thereby avoid an increase in study costs. Therefore, the Maryland Health Care Commission should not place limits that reduce the ability of non-SOS hospitals providing primary PCI to accrue participants for non-primary PCI. Specifically, the limit of six participating hospitals should be lifted. Similarly, the requirement that urban hospital applicants have a 2-year primary PCI waiver should be eliminated so that there is only one standard throughout the state.

While we agree that rigorous standards for applicants are appropriate, we believe that requiring a follow-up rate of 98% is unrealistic and virtually unattainable. In clinical studies, follow up over 90% is considered exceptional. The 98% rate will undermine the ability of the state to use the study results to make public policy.

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By making these recommended changes to the regulations, the Maryland Health Care Commission will improve access to elective PCI, particularly for minority and underserved populations, while achieving sufficient volumes that will help the state reach the minimum total cases required by the study protocol within the planned 3-year timeframe.

Again, thank you for the opportunity to comment on these regulations and thereby support the State's efforts to ground its health care public policy in sound and scientifically valid medical evidence.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Sexton', with a stylized flourish at the end.

Kevin J. Sexton
President & CEO